

November 25, 2002

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Director, Center for Device and Radiological Health (CDRH)
Dockets Management Branch (HFA-305)
Food and Drug Administration
5601 Fisher Lane room 1061
Rockville, MD 20852

Dear Dr. Feigal:

Thank you for the opportunity to comment to the FDA on Open-But-Unused Single-Use Medical Devices (OBU SUDs)—those devices whose sterility has been compromised and/or whose package has been opened but which have not been in contact with blood & body fluids. Your efforts to solicit comments and information from interested parties about opinions and current practices will surely assist us all in the long run with regard to the development of sound regulatory policy.

We have carefully reviewed the CDRH Final Guidance issued August 14, 2000 (65 Code of Federal Regulations {CFR} 49583) stating the agency's enforcement priorities for SUDs reprocessed by Third Parties and Hospitals, which included guidance on reporting, tracking, quality assurance and labeling. Specifically, regulatory requirements under the Food, Drug & Cosmetic Act include:

- Establishment registration and device listing (CFR, part 87)
- Good Manufacturing Practice (GMP) under the Quality System regulation (21 CFR, part 820)
- Device labeling (21 CFR, part 801)
- Submission of adverse events reports under the Medical Device Reporting (MDR) regulation (21 CFR, part 803)
- Medical device tracking (21 CFR, part 821)
- Correction and removals (21 CFR, part 806)
- Premarket requirements (21 CFR, parts 807 & 814)

Also, the recently (10/02) signed legislation (HR 5651) has further strengthened Device Labeling and Premarket Notification requirements.

These issues have been widely discussed and debated by manufacturers, reprocessors, hospitals and patients. Headline articles noting that "according to published data from a recent FDA telephone survey of all hospitals, more than 24% of all US hospitals reuse Single-Use-Devices" have focused additional attention on the matter. Some parties seized on this as evidence of some illegal or improper activity as only those reading the entire article learned that indeed the items labeled Single Use had in fact been used for the first time after having been resterilized/reprocessed by either third party registered reprocessors (85%) or hospitals meeting FDA reprocessing standards (15%).

A. General Background

Why is the SUD issue an ongoing contentious one?

1. **Hospitals have been successfully reprocessing, resterilizing and reusing medical devices for decades while providing safe, high quality care.** Clearly, with the introduction of disposable

devices and new materials, additional questions have been raised about safety, ethics, environmental concerns and costs associated with their reuse.

2. The FDA requirements APPLY ONLY to hospitals and do not apply to Ambulatory Surgery Centers (ASCs) or private physicians' offices. Especially in NYS, ASCs have put a significant strain on community based, not-for-profit hospitals by routinely sending them the most difficult clinical cases as well as many medically indigent patients (the uninsured and underinsured). This has focused attention on the fact that the rapidly proliferating ASCs (over 200 have opened in NYS in the last five years) are already subject to fewer regulatory constraints and specifically are exempt from FDA Reprocessing of Single-Use Device requirements. Finally, the media reports that there is no FDA monitoring of ASC compliance with Quality System regulations which apply to all hospitals.

FDA materials state that the regulations have been promulgated in the name of “the safety and the health of the public—based on good science and equitable to all parties” (FDA,CDRH, 8-2000). Further, in the words of the agency: “While the FDA is aware that Health Care facilities other than hospitals reprocess devices labeled for single use...the agency surveillance is limited to third party processors and hospitals.” Does the potential re-use of SUDs such as Phaco needles (classified as moderate risk) routinely used in ASCs doing cataract extractions and keratome blades (low risk) used for the increasingly common LASIK laser eye surgery, pose any less of a danger in an ambulatory surgery center than in a hospital? Is the risk or science different in the case of different kinds of providers?

3. There is an ongoing debate over the impact of the regulations on the environment and on efforts to limit rising health care costs as there is a plethora of data to support the premise that reuse saves both money and the environment. The periodical, *Infection Control Today*, noted in a recent issue: “If just 1 or 2% of all disposable devices used in the US today were reprocessed, the healthcare industry would save a billion dollars every year.” This does not include the related savings of disposal of medical waste. Ever-tightening restrictions have contributed to the increasing strain on hospitals' limited financial resources. Even when purchasing from licensed third party reprocessors, the cost of a reprocessed SUD is approximately 50% of the original price.

4. The profit motive of device manufacturers. The prices of disposables have been known to drop when a hospital informs its suppliers that it is looking into reprocessing. Some Original Equipment Manufacturers (OEMs) readily state that they label devices for single use only as a marketing strategy realizing that the device could potentially be reused. In some cases, the same, or substantially equivalent device, which has been previously labeled “multiple-use,” is suddenly labeled as a SUD. Some devices have been so labeled even though they have discrete properties that would likely make them safe for reuse post-sterilization—such as those which are solid stainless steel. Often, the OEMs have chosen not to undertake the expensive and time-consuming testing necessary to establish that a device can safely be used more than once as there is an economic incentive NOT to do so. Proposals suggesting that the original device makers be required to submit public documents explaining why a device is labeled as single-use--have not advanced. Many have noted that the label “single-use” is NOT a government requirement—it is exclusively in the purview of the manufacturer.

5. The patient safety questions surrounding reuse have never been definitively answered. In 2000, the GAO (GAO/HEHS-00-123) reported that clinical evidence indicates that certain devices

can be reprocessed safely. Similarly, journal articles have suggested that careful reprocessing of appropriate SUDs has not been demonstrated to be a public health risk as there are many types of devices that can and are effectively reprocessed and reused. It is reported that, across the entire country, new devices account for several thousand more reports of patient injury and device malfunction than reprocessed devices. On the other side of the debate, there has been Congressional testimony that “reuse is nothing more than recycling medical waste.”

B. Experience and Policy at the New York Eye and Ear Infirmary (NYEEI)

1. POLICY:

The Infirmary takes all safety regulations to the limit of the regulatory intent. In the case of SUDs, for example, even non-invasive items such as DVTs (Deep Vein Thrombosis--an externally applied legging type of pressure support to prevent clotting during certain surgical procedures) are sent to a third party licensed reprocessor. Similarly, although the FDA has not regulated the use of OBU SUDs to date, an OBU SUD Infirmary Policy and Procedure applies to the entire hospital. Many of these items are made of metal or another inorganic material, and while labeled “Single Use,” lend themselves to be safely resterilized/ reprocessed by licensed, registered third party reproducers after they have been Opened But are Unused. A limited number of devices labeled by the OEM as a SUD can be safely resterilized/reprocessed by a registered, licensed third party reprocessor and then safely used, for the first time. These items do not need to be discarded. Such a list of items used here includes:

Drill bits, burrs, ophthalmic knives, Bovie tips, laser probes (pending approval), phaco tips, custom surgical packs, phacoemulsification needles and endoilluminators.

However, OBU SUDs such as implants and breathing circuits (anesthesiology tubes) are NOT sent to be resterilized/reprocessed as these items might be subject to degradation during the resterilization process. Similarly, no OBU lumened SUDs are sent to be resterilized/reprocessed.

In the absence of regulation, this multi-faceted approach has served both our patients and the Infirmary extremely well.

2. PERSONNEL RESPONSIBLE for OBU SUD POLICY AND DECISION-MAKING.

The physician Medical Director directs all aspects of quality improvement and quality assurance activities and is directly involved with resterilizing/reprocessing activities. He is assisted by the Vice President for Patient Care and the OR Director. The designated authority for these policies lies with the above parties and the hospital’s Infection Control Committee, a multi-disciplinary committee which consists of clinical and operational staff including OR and Central Sterile Service staff.

The team monitors OBU SUD reprocessing quality assurance and improvement activities and recommends strategies for improving performance and reports the findings in accordance with the requirements of JCAHO standards--including those on ‘Surveillance’ and ‘Prevention and Control of Infection.’ These activities and recommendations are also reviewed by the performance improvement oversight committee, the Medical Board staff and the governing body.

3. HOW THE HOSPITAL DETERMINES IF A OBU SUD IS CONTAMINATED

We make certain that no item has been exposed to blood and body fluids, that it has not been dropped on the floor and that it has not been touched or exposed to any other source of contamination. As described above, only designated devices are resterilized/reprocessed by third party reprocessors in instances where the package was opened—whether inside or outside of a sterile field—and the device was not used for whatever reason. This applies to devices that have been removed from their sterile packaging, but have not touched a patient nor have been contaminated in any manner. OBU SUDs not meeting these criteria are discarded.

4. SUMMARY: OBU SUDs AT THE INFIRMARY

Our foremost concerns in this and others policy matters are to provide and promote safety in the care of our patients and to protect the public. In that context, we safely use for the first time some resterilized/reprocessed OBU SUDs; contaminated items are discarded. The hospital policy states that a licensed, registered third party reprocessor will be responsible for ct addresses cleaning/decontamination and related sterilization issues, testing for functionality, re-packaging and relabeling. As noted, we follow all safe practice guidelines to maximize patient safety and welfare. It is also important to the Infirmary to find cost savings where appropriate in order that we may maximize our mission to provide quality health care services in the community.

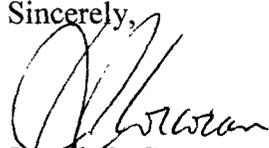
C. Recommendations

The entire SUD issue is a complex one that requires striking a balance between environmental, cost and patient safety issues while allowing for cost savings to occur where appropriate. Additional information should be gathered and better research conducted regarding the efficacy of existing practice regarding OBU SUDs before additional regulations are written. The government, health care providers and patients will all benefit from such a science-based approach. Many years of experience at the NYEEI clearly suggest that **specific OBU medical devices labeled as SUDs can be resterilized/reprocessed and then be safely used, for the first time**. There has not been a single adverse event related to our current OBU SUD policy.

We respectfully suggest that the FDA need not promulgate any regulations on this matter at this time.

Thank you again for the opportunity to comment on these important policy issues.

Sincerely,



Joseph P. Corcoran
President & CEO

cc: R. Andrew
E. Esquieres, R.N.
J.R. Rosenthal, MD
S. Tennaro, Ed. D.